

A study to find the optimal dose for vitamin K supplementation in patients being treated with vitamin K antagonists to create an anti-coagulation effect

Submission date 17/03/2008	Recruitment status No longer recruiting	☒ Prospectively registered
Registration date 31/03/2008	Overall study status Completed	☐ Protocol
Last Edited 23/10/2020	Condition category Haematological Disorders	☐ Statistical analysis plan
		☒ Results
		☐ Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Protocol serial number

P07.243

Study information

Scientific Title

A study to find the optimal dose for vitamin K supplementation in patients being treated with vitamin K antagonists to create an anti-coagulation effect

Acronym

VIKS-2A

Study objectives

The anti-coagulation treatment with vitamin K antagonists will be more stable and safer with the supplementation of a low daily dose of vitamin K.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval received from the Medical Ethics Committee of Leiden University Medical Center on the 4th March 2008.

Study design

Randomised double-blind placebo-controlled single-centre trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Anti-coagulant treatment

Interventions

The participants will be randomly allocated to the following four groups in equal numbers:

Group 1: 100 µg vitamin K1 (oral), 1 capsule per day (1 dd)

Group 2: 150 µg vitamin K1 (oral), 1 dd

Group 3: 200 µg vitamin K1 (oral), 1 dd

Control group: placebo (oral), 1 dd

The duration of the treatment is flexible, as is the inclusion period. Follow-up will take place six months after the closure of the inclusion period. This means the first patients will receive vitamin K or placebo for six months and the time the inclusion will take. The last patients will only receive vitamin K or placebo for six months.

Intervention Type

Supplement

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Vitamin K supplementation

Primary outcome(s)

Quality of anti-coagulant treatment expressed as time in therapeutic range. Duration of follow-up: until six months after the closure of the inclusion period.

Key secondary outcome(s)

Number of INRs in therapeutic range. Duration of follow-up: until six months after the closure of the inclusion period.

Completion date

31/03/2009

Eligibility

Key inclusion criteria

1. Start treatment with vitamin K antagonists less than four weeks before inclusion
2. Treatment with vitamin K antagonists for a minimal period of six months, with the therapeutic range of International normalised ratio (INR) between 2.5 and 3.5
3. Aged between 18 and 85 years, either sex
4. Measurement of the INR by the Thrombosis Service Leiden
5. Informed consent

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Upper age limit

85 years

Sex

All

Total final enrolment

400

Key exclusion criteria

1. Treatment for liver failure
2. Dialysis, both peritoneal and haemodialysis
3. Pregnancy, or wish to get pregnant; lactational period
4. Known to have a chronic condition with a life expectancy of less than six months
5. An expected interruption of treatment with oral anti-coagulants for one week or longer
6. Participation in the self-management protocol

Date of first enrolment

01/04/2008

Date of final enrolment

31/03/2009

Locations

Countries of recruitment

Netherlands

Study participating centre

Leiden University Medical Center

Leiden

Netherlands

2300 RC

Sponsor information

Organisation

Netherlands Heart Foundation (Nederlandse Hartstichting) (The Netherlands)

ROR

<https://ror.org/05nxhgm70>

Funder(s)

Funder type

Charity

Funder Name

Netherlands Heart Foundation (Nederlandse Hartstichting) (The Netherlands)

Results and Publications

Individual participant data (IPD) sharing plan**IPD sharing plan summary**

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/04/2011	23/10/2020	Yes	No